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MEDTRONIC, INC.
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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,792	SIGG ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 27, 2007 has been entered. Claim 27 has been cancelled. Claims 29 and 30 are new and have been added. Claims 1-26 and 28-30 are pending.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application, by application number and filing date, is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath/declarations do not have the correct statement with respect to the duty to disclose. This applies to all applications, not just reissue applications.

A CORRECT STATEMENT should read, "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

Therefore, the polymeric layer extending over the coil electrode must be shown or the feature(s) canceled from the claim(s). Also, a porous layer overlaying a layer of catalytic agent must be shown or the feature(s) canceled from the claim(s) and a plug having a layer of catalytic agent on an outer surface of the plug must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the Examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 6-7, 10-11, 13 and 22 are objected to because of the following informalities: the claims contain inadvertent typographical errors rendering the language awkward and/or grammatically incorrect. As to Claim 6, the Examiner suggests changing lines 2-4 of the claim to read something similar to, "wherein the electrode is coupled to a one of the one or more conductors and is overlaying the outer surface of the polymeric layer; and wherein the one of the one or" instead. Similar changes should also be made to Claims 7 and 10-11. As to Claim 13, line 2, the Examiner suggests changing "wherein the electrode being" to read, "wherein the electrode is" instead. As to Claim 22, line 7, the Examiner suggests changing "the electrode being coupled to a one of the one or more conductors, adapted to" to read, "the electrode coupled to a one of the one or more conductors and adapted to" instead. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 13 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. As to Claim 13, although Applicant's disclosure provides support for the outer surfaces of the coil electrode including an overlaying layer of a catalytic agent (see, for example, page 7, paragraph 27 of Applicant's disclosure), the Examiner is unable to find, throughout Applicant's disclosure, support for an embodiment of the device where the coil electrode includes an overlaying layer of a polymeric layer.

9. As to Claim 23, the Examiner notes an embodiment of Applicant's invention that includes an implantable medical electrical lead comprising a tip electrode that includes a porous side wall and a polymeric plug within the side wall (see, for example, Fig. 8B of Applicant's disclosure). The Examiner is unable to find however, throughout Applicant's disclosure, support for an embodiment of the implantable medical electrical lead where the lead comprises a coil electrode and where the coil electrode includes a porous side wall and a polymeric plug held within the porous side wall of the coil electrode. Claim 24 depends from Claim 23 and the deficiencies of Claim 23 are imputed to all dependent claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. ***Claims 1-14, 19-22, 25, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al. (U.S. 5,928,277) (herein Laske) in view of Batchelor et al. (U.S. 2002/0115559) (herein Batchelor).*** As to Claims 1-12, 14, 19-22, 25, 28 and 30, Laske expressly discloses an implantable electrical lead, read as an implantable therapy delivery and/or diagnostic device (see Laske Fig. 1, Abstract and column 1, lines 5-7 and lines 40-63) comprising fixation elements 12 adapted to secure the device to an implant site (see Laske column 2, lines 10-15) and one or more elongate conductors 36A extending within the device. The device of Laske further includes a silicone rubber, polyurethane or other biocompatible elastomer multi-lumen lead body, read as a polymeric layer 20 which forms the device body synonymous to that disclosed by Shoberg et al. (U.S. 5,584,873) (herein Shoberg). A defibrillation electrode 18 is positioned along the outer surface of the polymeric layer 20 and it is specified to comprise multiple coil turns (see Laske Figs. 2-3, column 2, lines 28-67 and column3, lines 1-11). Laske discloses the claimed invention as previously discussed except that it is not specified that the device include a layer of a catalytic agent, having nitrite reductase and/or nitrate reductase, or nitrosothiol reductase activity, present on the outer surface of the polymeric layer 20 such that the catalytic agent converts nitrite/nitrate or nitrosothiols found in blood to nitric oxide.

Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that by providing biocatalysts or biomimetic catalysts on blood contacting surfaces of implantable biomedical devices prevents platelet activation and adhesion onto these surfaces, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23).

Batchelor further teaches that a material in accordance with the antithrombogenic desirability may be made or manufactured in one of a plurality of embodiments. In a first embodiment, the material includes a polymeric layer having a layer of a catalytic agent where the double layer material is attached to the surface of a metal or polymeric implantable medical device. In a second embodiment, a polymeric implantable medical device itself supplies the polymeric layer for the material and only a catalytic agent is attached to the surface of the polymeric device. In either of these embodiments, Batchelor specifies that the polymeric layer may include a bulk matrix containing a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent (see Batchelor Figs. 1 and 4 and page 2, paragraphs 18-21 and paragraph 24). It is inherent or at least obvious to one having ordinary skill in the art that in this embodiment of Batchelor, the polymeric layer having the layer of

biocatalysts or biomimetic catalysts on its surface would include a plurality of pores extending there through, otherwise the lipophilic salts or nitrite/nitrate or nitrosothiols would not be able to "continuously leak to the catalytic surface of the material" as specified by Batchelor (see Batchelor page 2, paragraphs 24-26).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer surface of the leady body of Laske to include any of the antithrombogenic embodiments taught by Batchelor, as discussed above, since such modifications to the outer surface of the device would provide an antithrombogenic implantable therapy and/or diagnostic device which prevents platelet activation and adhesion, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials. To clarify, it would have been prima facie obvious for the reasons previously discussed to either attach the double layer antithrombogenic material of Batchelor to the surface of the polymeric layer 20 of Laske and/or it would have been prima facie obvious for the reasons previously discussed to form the polymeric layer 20 of Laske as a double layer antithrombogenic material of Batchelor, where in either modification, the polymer layer of the double layer antithrombogenic material includes a bulk matrix containing a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent. It is inherent that in the modified device of Laske, the catalytic agent present on the outer surface of the lead body would be exposed between coil turns of electrode 18 since the coil turns are wound about and preferably slightly embedded into the outer surface of the lead body in a spaced relationship to each other (see Laske Figs. 2-3 and column 3, lines 1-2).

13. As to Claim 13, in addition to the arguments previously presented, Batchelor further specifies that the catalytic layer may be attached to implantable medical devices having metal blood contacting surfaces (see Batchelor Fig. 4, page 2, paragraphs 18-25 and page 3, paragraph 46). It would have been obvious to one having ordinary skill in the art to modify the device of Laske,such that any metal or polymer blood contacting surface of the device includes a layer of a catalytic agent as taught by Batchelor, since such modifications to the outer surfaces of the device would provide an antithrombogenic implantable therapy and/or diagnostic device which prevents platelet activation and adhesion at all blood contacting surfaces, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials.

14. ***Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laske in view of Batchelor as applied to claims 1 above, and further in view of Halperin et al. (U.S. 5,564,434) (herein Halperin).*** The previously modified Laske reference discloses the claimed invention as discussed above except that the device does not further comprise a physiological sensor capsule coupled to the one or more conductors where the outer surface of the polymeric layer overlays a portion of the sensor capsule.

Halperin, however, teaches that it is well known in the art to employ a metal housed physiological sensor module, read as a capsule 20 coupled to one or more extending conductors 14 and 16 in a medical lead in order to enable rate responsive pacing functions employing temperature or pressure sensing (see Halperin Abstract, Figs. 2 and 3 and column 7, lines 19-67). Batchelor further specifies that the invention (the double layer antithrombogenic material/film including a polymeric layer and biocatalyst or biomimetic catalyst coating) may be applied to

most medical devices with a biocompatible surface such as a polymer/metal catheter or biosensor (see Batchelor Abstract and page 2, paragraph 22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Laske in view of Batchelor and Halperin to include a physiological sensor capsule coupled to the one or more conductors where the outer surface of the biosensor capsule includes a double layer antithrombogenic material/film in order to allow rate responsive pacing/defibrillation utilizing parameters such as temperature and pressure and to provide the sensor capsule with improved biocompatibility.

15. ***Claims 16-18 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske in view of Batchelor as applied to claims 1 above, and further in view of Stokes (U.S. 4,506,680) (herein Stokes '680).*** In addition to the arguments previously presented, the implantable therapy delivery and/or diagnostic device of Laske further includes a distal tip electrode 10 coupled to an elongate conductor as disclosed by Shoberg (see Laske Fig. 1, column 1, lines 40-57 and column 2, lines 10-27). The previously modified Laske reference discloses the claimed invention as previously discussed except it is not specified that the device further include a polymeric plug within the lead body 20 that contains a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can lead to the layer of the catalytic agent present on the outer surface of the lead body 20.

Stokes '680, however, teaches that it is well known in the art to provide an implantable pacing device with a porous distal tip electrode 22, 22' and a silicone rubber plug 38 held within the lead body 10 such that lipophilic salts leak from a reservoir of the plug 38, through the porous distal tip electrode 22, 22' and out the distal tip of the lead body 10 (see Stokes Figs. 1-2

and column 3, lines 5-57). Stokes '680 teaches that by constructing the device in this manner the amount of energy required to stimulate the heart is substantially reduced and further that that the construction promotes low impedance at the distal tip of the device such that detection of electrical heart activity is facilitated (see Stokes '680 Abstract and column 4, lines 20-48). It is inherent that the lipophilic salts leached out from the distal tip are leached out "to the outer layer of the lead body" since the salts exit the tip of the lead and then reside outside the distal end of the lead body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Laske in view of Batchelor and Stokes '680 to include a porous distal tip electrode and a silicone rubber plug held within the lead body such that lipophilic salts leak from a reservoir of the plug, through the porous distal tip electrode and out the distal tip of the lead body to the outer surface of device providing an improved device for cardiac rhythm management.

16. ***Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laske in view of Batchelor as applied to claims 22 above, and further in view of Fearnot et al. (U.S. 5,609,629) (herein Fearnot).*** The previously modified Laske reference discloses the claimed invention as previously discussed except that it is not specified that the device include a porous layer overlaying the layer of catalytic agent.

Fearnot, however, teaches that it is well known in the art to overlay a nitric oxide promoting bioactive layer 18 of an implantable medical device 10 with a porous layer 20 such that the release of bioactive substance from layer 18 can be a very precise controlled release (see Fearnot Abstract, Fig. 1, column 3, lines 66-67, column 3, lines 1-29, column 5, lines 40-42, column 6, lines 24-30, column 7, lines 1-45, column 8, lines 55 and column 9, lines 28-63). It

would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Laske in view of Batchelor and Fearnot such that the device includes a porous layer overlaying the layer of catalytic agent in order to precisely control the rate nitric oxide is released into the blood stream from the catalytic agent.

17. ***Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fearnot in view of Batchelor.*** Fearnot expressly discloses an implantable therapy delivery and/or diagnostic device 10 comprising a body including a side wall 20 having a plurality of pores and a polymeric plug 14 held within the porous side wall 20 and including a nitric oxide promoting bioactive layer 18 (see Fearnot Abstract, Fig. 1, column 3, lines 66-67, column 3, lines 1-29, column 5, lines 40-42, column 6, lines 24-30, column 7, lines 1-45, column 8, lines 55 and column 9, lines 28-63). Fearnot discloses the claimed invention except that it is not specified that layer 18 include a layer of a catalytic agent, having nitrite reductase and/or nitrate reductase, or nitrosothiol reductase activity, present on the outer surface of the polymeric layer 20 such that the catalytic agent converts nitrite/nitrate or nitrosothiols found in blood to nitric oxide.

Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that by providing biocatalysts or biomimetic catalysts on blood contacting surfaces of implantable biomedical devices prevents

platelet activation and adhesion onto these surfaces, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials. Batchelor further teaches that coating these biocatalysts or biomimetic catalysts on the surface of biomedical materials is an improvement over NO-releasing materials well known in the art because they are relatively inexpensive to manufacture, have improved biocompatibility and are easier to store (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nitric oxide promoting bioactive layer Fearnot to include a layer of biocatalysts or biomimetic catalysts as taught by Batchelor, since such a modification would provide an improved antithrombogenic implantable therapy and/or diagnostic device which is inexpensive to manufacture and easy to store.

18. ***Claims 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes et al. (U.S. 5,282,844) (herein Stokes '844) in view of Batchelor.*** Stokes '844 discloses an implantable medical electrical lead, read as an implantable therapy and/or diagnostic device (see Stokes '844 Abstract and Fig. 1) comprising tines, read as fixation elements 26 adapted to secure the device to an implant site (see Stokes '844 Figs. 2-3 and column 7, lines 4-8), one or more elongate conductors 28 extending within the elongated lead body 10 of the device (see Stokes '844 Figs. 2 and 6 and column 8, lines 48-56) and a polymeric insulation tubing, read as a polymeric layer 12 overlaying a portion of the device in proximity to the implant site (see Stokes '844 Figs. 1-2, 4, 6, 9 and 11, column 6, lines 49-52, column 7, lines 35-38 and column 8, lines 11-13). Stokes '844 discloses the claimed invention as discussed above except that the outer surface of the polymeric layer 12 is not disclosed to comprise a layer of a catalytic agent, having

a nitrite reductase and/or nitrate reductase or nitrosothiol reductase activity such that the catalytic layer converts nitrite/nitrate or nitrosothiols found solely in the blood to nitric oxide.

Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that by providing biocatalysts or biomimetic catalysts on blood contacting surfaces of implantable biomedical devices prevents platelet activation and adhesion onto these surfaces, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23).

Batchelor further teaches that a material in accordance with the antithrombogenic desirability may be made or manufactured in one of a plurality of embodiments. In a first embodiment, the material includes a polymeric layer having a layer of a catalytic agent where the double layer material is attached to the surface of a metal or polymeric implantable medical device. In a second embodiment, a polymeric implantable medical device itself supplies the polymeric layer for the material and only a catalytic agent is attached to the surface of the polymeric device. In either of these embodiments, Batchelor specifies that the polymeric layer may include a bulk matrix containing a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent (see Batchelor Figs. 1 and 4 and page 2,

paragraphs 18-21 and paragraph 24). It is inherent or at least obvious to one having ordinary skill in the art that in this embodiment of Batchelor, the polymeric layer having the layer of biocatalysts or biomimetic catalysts on its surface would include a plurality of pores extending there through, otherwise the lipophilic salts or nitrite/nitrate or nitrosothiols would not be able to "continuously leak to the catalytic surface of the material" as specified by Batchelor (see Batchelor page 2, paragraphs 24-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer surface of the leady body of Stokes '844 to include any of the antithrombogenic embodiments taught by Batchelor, as discussed above, since such modifications to the outer surface of the device would provide an antithrombogenic implantable therapy and/or diagnostic device which prevents platelet activation and adhesion, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials.

19. ***Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Borgersen et al. (U.S. 20010018607) (herein Borgersen) in view of Batchelor.*** Borgersen discloses an implantable therapy delivery and/or diagnostic device 20 comprising a fixation element 48 adapted to secure the device 20 to an implant site, one or more elongate conductors extending within the device and an insulated body, read as a polymeric layer 40 fabricated of a plurality of co-extruded biocompatible elastomers (see Borgersen page 4, paragraph 35) such as polyurethane (see Borgersen page 6, paragraph 47) overlaying multiple lumens (see (Borgersen Figs. 2-3). Borgersen discloses the claimed invention as discussed above except that it is not specified that the polymeric layer 40 comprise a layer of a catalytic agent, having a nitrite

reductase and/or nitrate reductase or nitrosothiol reductase activity such that the catalytic layer converts nitrite/nitrate or nitrosothiols found solely in the blood to nitric oxide.

Batchelor, however, teaches the use of biocompatible materials (i.e. polymers, metals, stainless steels, carbon and the like) provided with biocatalysts or biomimetic catalysts on their surface that have nitrite reductase, nitrate reductase and/or nitrosothiol reductase within such that the biocatalysts or biomimetic catalysts on the surface of such biocompatible materials can act on endogenous nitrite/nitrate or nitrosothiols within the blood creating a local increase in the nitric oxide levels at the surface of the material. Batchelor specifies that the biomimetic catalyst may comprise Cu(II) metal ion ligand complex. Batchelor specifies that by providing biocatalysts or biomimetic catalysts on blood contacting surfaces of implantable biomedical devices prevents platelet activation and adhesion onto these surfaces, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials (see Batchelor Abstract, lines 3-12 and page 1-2, paragraphs 4-23).

Batchelor further teaches that a material in accordance with the antithrombogenic desirability may be made or manufactured in one of a plurality of embodiments. In a first embodiment, the material includes a polymeric layer having a layer of a catalytic agent where the double layer material is attached to the surface of a metal or polymeric implantable medical device. In a second embodiment, a polymeric implantable medical device itself supplies the polymeric layer for the material and only a catalytic agent is attached to the surface of the polymeric device. In either of these embodiments, Batchelor specifies that the polymeric layer may include a bulk matrix containing a reservoir of lipophilic salts or nitrite/nitrate or nitrosothiols that can leak to the layer of catalytic agent (see Batchelor Figs. 1 and 4 and page 2,

paragraphs 18-21 and paragraph 24). It is inherent or at least obvious to one having ordinary skill in the art that in this embodiment of Batchelor, the polymeric layer having the layer of biocatalysts or biomimetic catalysts on its surface would include a plurality of pores extending there through, otherwise the lipophilic salts or nitrite/nitrate or nitrosothiols would not be able to "continuously leak to the catalytic surface of the material" as specified by Batchelor (see Batchelor page 2, paragraphs 24-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the outer surface of the leady body of Borgersen to include any of the antithrombogenic embodiments taught by Batchelor, as discussed above, since such modifications to the outer surface of the device would provide an antithrombogenic implantable therapy and/or diagnostic device which prevents platelet activation and adhesion, thereby lowering thrombus formation and other complications associated with interactions between blood and foreign materials.

Response to Arguments

20. Applicant's arguments with respect to claims 1-26 and 28 have been considered but are moot in view of the new ground(s) of rejection.

21. The Examiner notes, that newly presented Claim 30 is identical to the limitations of a prior version of Claim 1, previously presented to the Office via Amendment on August 24, 2006. These limitations were rejected in the Final Rejection of October 27, 2006 as being unpatentable over Stokes '844 in view of Batchelor and as being unpatentable over Borgersen in view of Batchelor. In addition to the new rejection of these limitations as being unpatentable over Laske in view of Batchelor, the limitations stand rejected as being unpatentable over Stokes '844 in

view of Batchelor and as being unpatentable over Borgersen in view of Batchelor, as discussed above in this Office Action.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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